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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,354	04/25/2001	HRISANTHI IKONOMIDOU	HRIS-1	7746
23599	7590	12/03/2003	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,354	IKONOMIDOU, HRISSANTHI	
	Examiner	Art Unit	
	Anand U Desai	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 8-33 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Invention I in response to Restriction filed on October 27, 2003 is acknowledged. The traversal is on the ground(s) that the subject matter of the claims does have unity of invention and search of the claims of inventions I-III, and IX would not represent a serious search burden for the patent office. This is not found persuasive because the inventions are directed to methods of inhibiting different receptors, with different receptor antagonists.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-33, and 35-37 are withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant Application No. 09/830,354, filed on April 25, 2001.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. A statement stating this is a national stage application should be entered following the title of the invention or as the first sentence of the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the term “alkoxy-phenyl-benzodiazepine” is undefined. Which position are the substituents placed?

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “fluorowillardiine” in claim 7 is used by the claim to mean “an AMPA receptor channel blocker”, while the accepted meaning is “generally referred to as an agonist for the AMPA receptor.” (Fletcher, E. and Lodge, D. Pharmacol. Ther. Vol. 70, No. 1, pg. 65-89, particularly pg. 75, 3rd paragraph in Selective Agonists section). The term is indefinite because the specification does not clearly define the term.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonoï, T. et al. (J. of Biol. Chem. 269 (25): 16989-16922 (1994)) in view of Yoshioka, A. et al. (J. of Neurosci. Research 46:164-172 (1996)) in further view of Fletcher E.J. and Lodge, D. (Pharmacol Ther. 70(1):65-89 1996). Gonoï, T. et al. teach the expression of α -amino-3-hydroxy-5-methyl-4-isoxazolepropionate (AMPA) receptors in insulinoma cell line MIN6 (see pg. 16990-16991, 1st paragraph and 5th paragraph). Gonoï, T. et al. does not teach the use of AMPA receptor antagonist to treat tumor progression. Yoshioka, A. (1996) et al. suggests a lack of susceptibility to cellular excitotoxicity, as a factor in neural tumor progression (pg. 164, 2nd paragraph of Introduction section, and pg. 171, last paragraph of Discussion section). Cellular excitotoxicity has been demonstrated to occur through glutamate-gated ionotropic receptors and blocked by antagonists to glutamate-gated ionotropic receptors (pg. 164, 2nd paragraph in Introduction section). Yoshioka, A. et al. does not teach the specific AMPA receptor antagonists. Fletcher, E.J. et al. teaches specific AMPA receptor antagonists, such as 2,3-benzodiazepines (current application, claims 3, 4), 6-nitro-7-cyano-quinoxaline-2,3-dione (CNQX) (current application, claims 3, 5), and Joro spider toxin (JSTX) (current application,

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claims 3, 6, 7) (pg. 76-79, section on Pharmacology of defined non-NMDA receptors).


Therefore, it would have been obvious to the person having ordinary skill in the art to treat cancer administering an inhibitor of the AMPA receptor complex (current application, claims 1-7).

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonoï, T. et al. (J. of Biol. Chem. 269 (25): 16989-16922 (1994)) as applied to claims 1-7 above, and further in view of Oftebro et al. (U.S. Patent 5,049,396 September 17, 1991). Oftebro et al. teaches the use of combination therapy to treat malignant tumors. Oftebro et al. teaches the use of an intercalating drug such as cisplatin with another anti-cancer composition (column 1, lines 40-58, and column 4, Experiments 1 and 2). Therefore, it would have been obvious to the person having ordinary skill in the art to treat cancer administering an inhibitor of the AMPA receptor complex with another anti-cancer composition (current application, claim 34).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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November 26, 2003

A handwritten signature in black ink, consisting of a large, stylized capital 'A' followed by a capital 'O' and a horizontal line extending to the right.